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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/529,520	11/16/2005	Christopher B. Wood	10103-016-999	6157

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EXAMINER	
JAVANMARD, SAHAR	
ART UNIT	PAPER NUMBER
1617	
MAIL DATE	DELIVERY MODE
10/16/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/529,520	WOOD ET AL.	
	Examiner	Art Unit	
	SAHAR JAVANMARD	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 July 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-37* is/are pending in the application.

4a) Of the above claim(s) *1-16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

This Office Action is in response to applicant's arguments filed on July 10, 2008. Claim(s) 1-37 are pending. Claim(s) 17-19 have been amended. Claim(s) 20-37 have been newly added. Claim(s) 17-37 are examined herein.

Response to Arguments

In view of Applicant's amendments The objections to claims 18 and 19 are hereby withdrawn.

Applicant's arguments with respect to the 102(b) rejection of claims 17 and 18 as being anticipated by Montgomery et al. (US Patent No. 5,384,310) has been fully considered but is not persuasive. Applicants argue that the preamble should be given patentable weight. Examiner respectfully notes that the preamble in fact is "pharmaceutical composition" and is given weight in examination, however, "treating lupus" is considered an intended use and is not given patentable weight as set forth in the previous Office Action. Therefore, for reasons of record, the 102(b) rejection is hereby maintained and is included in the office action below for Applicant's convenience.

Applicant's arguments with respect to the 103(a) obviousness rejection of claim 19 has been fully considered but is not persuasive. Applicant argues that "…Examiner's reliance on *In re Kerkhoven* is misplaced because neither the '310 patent nor the '229

patent teaches the use of clofarabine and rapamycin, respectively, as part of a pharmaceutical composition for the treatment of lupus".

Examiner respectfully notes that, as discussed above, the 102(b) rejection is maintained therefore the use of the '310 patent is not misplaced. The fact that the '229 patent teaches the combination of clofarabine and rapamycin in the treatment of cancer, exemplifies the motivation to combine the two agents in light of *In re Kerkhoven*. The reason or motivation to modify a reference may often suggest what the inventor has done, but for a different purpose or to solve a different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant. While there must be motivation to make the claimed invention, there is no requirement that the prior art provide the same reason as the applicant to make the claimed invention (see MPEP 2144).

The following modified rejections have been made In the Office action below, in light of Applicant's amendments.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 17, 18, 20-22, and 32-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Montgomery et al. (US Patent No. 5,384,310).

Examiner respectfully notes that no patentable weight is given for the "intended use" of the pharmaceutical composition containing clofarabine as recited in claims 17-18. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Montgomery teaches 2'-fluoro-2-substituted purine nucleosides, namely clofarabine (column 3, lines 25-39; claim 1), as anticancer agents. Further, Montgomery teaches that the compounds may be administered in a dosage regimen ranging from 10 mg to 1000 mg per day (column 11, lines 14-16).

Thus the limitations of claims 17-22 are met.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious

> at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 19, 23-31 and 35-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Montgomery et al. (US Patent No. 5,384,310) as applied to claims 17, 18, 20-22, and 32-34 above in view of Shelley (US Patent No. 5,491,229) in further view of .

Montgomery is discussed above.

Montgomery does not teach an immunomodulatory agent.

Shelley teaches 14-methylene rapamycin and its usefulness as an antifungal and anticancer agent as well as possessing immunomodulatory properties (column 1, lines 61-66).

The invention further provides a pharmaceutical composition comprising a compound of the formula (I) or a pharmaceutically acceptable salt thereof together with a pharmaceutically acceptable diluent or carrier. The composition is preferably for human use in tablet, capsule, injectable or cream form (column 9, lines 15-30).

Shelley does not teach other immunomodulatory agents such as methothrexate, leflunomide, cyclophosphamide, cyclosporine A, tacrolimus, mycophenolate, mofetil, and sirolimus.

Dingivan teaches immunomodulatory agents such rapamycin as well as methothrexate, leflunomide, cyclophosphamide, cyclosporine A, tacrolimus, mycophenolate, mofetil, and sirolimus [0191].

It would have been obvious to one of ordinary skill in the art at the time of the invention to have combined clofarabine as taught by Montgomery and further included an immunomodulatory agent. The motivation provided by Shelley, teaches rapamycin, a compound possessing both anticancer and immunomodulatory properties. Since both compounds can be used for the same purpose, namely cancer, one would expect with a reasonable degree of success that the combination will be just as successful, if not more.

The examiner respectfully points out the following from MPEP 2144.06:
"It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose ....[T]he idea of combining them flows logically from

their having been individually taught in the prior art.', *In re Kerkhoven*, 626 F.2d 846, 850,205 USPQ 1069, 1072 (CCPA 1980).

Furthermore, Dingivan teaches that rapamycin, methothrexate, leflunomide, cyclophosphamide, cyclosporine A, tacrolimus, mycophenolate, mofetil, and sirolimus are all immunomodulatory agents, therefore one in the art would expect with a reasonable degree of certainty that one immunomodulatory agent may be employed over another, in the absence of unexpected results.

Conclusion

Claims 17-37 are not allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SAHAR JAVANMARD whose telephone number is (571) 270-3280. The examiner can normally be reached on 8 AM-5 PM MON-FRI (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/S. J./

Examiner, Art Unit 1617

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617